DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group II in Paper No. 10 is acknowledged.

Claims 1-7 and 11-62 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 10.

Claims 8-10 are under examination in the instant office action.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 8-10 are rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility. The instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose the biological role of this protein or its significance.

It is clear from the instant application that the protein described therein is what is termed an "orphan protein" in the art. A DNA encoding that protein has been isolated because of its similarity to a known DNA. There is little doubt that, after complete characterization, this DNA and encoded protein may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete. The instant situation is directly analogous to that

which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediate obvious or fully disclosed "real world" utility. The court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion".

The instant claims are drawn to a purified polypeptide of as yet undetermined function or biological significance. It is clear from the instant application that the present invention relates to a human lipoxin A_4 receptor-like protein and "[i]t is an object of the invention to provide reagents and methods of regulating a human lipoxin A_4 receptor-like protein" (page 4, lines 27-28 of the instant specification). "The protein comprises 7 transmembrane domains" (page 8, line 10) and, therefore, appears to belong to the family of G-protein coupled receptors (GPCR). The specification asserts further that a human lipoxin A_4 receptor-like protein of SEQ ID NO: 2 is related to a family of lipoxin A_4 receptors, which are involved in induction of inflammatory response, for example (page 4, second paragraph). Analysis of the pattern of tissue expression of the novel claimed polypeptide reveals that it is "highly expressed in uterus, liver, placenta, and the gastrointestinal system" (page 68, lines 1-4). Finally, it is asserted that "[m]odulation of lipoxin A_4 receptor-like protein binding to its naturally occurring ligand can be used, for example, in the control of homeostasis, vascular reactivity, especially vasoconstriction, asthma,

and anaphylactic and allergic reactions in mammals, preferably in humans"(page 44, first paragraph of the instant specification).

In the absence of knowledge of the biological significance of this specific polypeptide, a human lipoxin A_4 receptor-like protein, there is no immediately obvious patentable use for it. The similarity of the disclosed polypeptide to members of lipoxin A_4 receptor family does not make the instant polypeptide useful or significant as the known polypeptides. There is no evidence of record, which associates the instant human lipoxin A_4 receptor-like protein with any diseases or disorders. It is a general knowledge that amino acid structure cannot necessarily predict the function of the protein: "Knowing the protein structure by itself is insufficient to annotate a number of functional classes and is also insufficient for annotating the specific details of protein function" (see Skolnick et al., Box 2 on page 36). There are numerous publications available for review that indicate that even two-amino acid substitution in a molecular structure of a protein can lead to total loss of a protein to bind a specific receptor (see, for example, Yan et al., 2000). Thus, the structural homology of the proteins of the present invention to the proteins with a known function cannot *a priori* be predictive and conclusive of a function of the claimed proteins.

Based on the information provided in the instant specification, it is obvious that the claimed polypeptide most probably belongs to a class of orphan GPCR, which lack a defined physiologically relevant ligand to control GPCR activity (see page 132 of Howard et al. 2001. TRENDS in Pharmacol. Sci., Vol. 22, No. 3, pp.132-140). Without knowledge of the natural ligand of the claimed lipoxin A_4 receptor-like protein, one would not know the specific pathway

that is regulated by this instant GPCR, and, consequently, not be able to use the claimed polypeptide to regulate any physiological function, for example.

Therefore, to employ the polypeptide in the future methods "of regulating a human lipoxin A_4 receptor-like protein" is not a real world utility because it would relate to a protein for which no specific biological function is known. The instant application also fails to demonstrate use of the protein as a marker for any disease or condition (which would be a real world use). Because the instant specification does not teach a biological activity of the protein, which supports a practical utility, one would not reasonably believe that the modulation of the instant polypeptide to its naturally occurring ligand, which is not disclosed in the instant specification, would be useful in control of hemostatis, vascular reactivity or any other physiological reactions, as implied by the specification. To employ a polypeptide of the instant invention in any of the disclosed methods would clearly be using it as the object of further research, which has been determined by the courts to be a utility, which, alone, does not support patentability. Since the instant specification does not disclose a credible "real world" use for the disclosed protein then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 8-10 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a clear asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. Claims 8 and 9 are rejected under 35 U.S.C. 102(a) as being anticipated by Elshourbagy et al. (WO 00/26339, 05/2000).

Claims 8 and 9 encompass a purified polypeptide comprising the amino acid sequence of SEQ ID NO: 2. Elshourbagy et al. disclose an amino acid sequence that has 100% sequence similarity to the instant sequence of SEQ ID NO: 2 (see a copy of the printout alignment attached to the instant office action). Therefore, Elshourbagy et al. anticipate claims 8 and 9.

With regards to the priority date, Applicant is advised that the instant application can only receive benefit under 35 U.S.C. § 120 from an earlier application which meets the requirements of 35 U.S.C. § 112, first paragraph, with respect to the now claimed invention.

35 U.S.C. § 120 states that:

> An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States, or as provided by section 363 of this title, which is filed by an inventor or inventors named in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the

> patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application.

Because the instant application does not meet the requirements of 35 U.S.C. § 112, first paragraph for those reasons given above, the priority to the earlier provisional application is denied. Therefore, the effective filing date of the instant application is established as the filing date of the instant application, which is 03/14/2001.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Elshourbagy et al. as applied to claims 8 and 9 above and also in view of Hopp et al (US Patent No. 5,011,912, 1991).

Claim 10 is directed to a fusion protein comprising a polypeptide of SEQ ID NO: 2. A polypeptide having 100% identical sequence to the instant SEQ ID NO: 2 is disclosed by Elshourbagy et al.. Elshourbagy et al. to not expressly describe a fusion protein comprising the disclosed sequence.

Hopp et al. disclose a fusion protein with N-terminal flag, useful for the purposes of protein purification (see the abstract, for example).

At the time the invention was made, it would have been *prima facie* obvious to a person of ordinary skill in the art to use the polypeptide of Elshourbagy et al. for the production of a fusion protein as disclosed by Hopp et al. One of ordinary skill in the art would have been motivated to do this for the purposes of protein purification or antibody production.

Conclusion

6. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 782-9306 for regular communications and (703) 782-9307 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)0. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D.
March 5, 2003

JOHN ULM
PRIMARY EXAMINER
GROUP 1600

GenCore version 5.1.3

M protein - protein search, using sw model

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(without alignments)
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red. No. is the number of results predicted by chance to have a score greater than or equal to the score of the result being printed, and is derived by analysis of the total score distribution.

SUMMARIES

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2	2500	100.0	470	21	AAY94268	Human G-protein co
3	2500	100.0	470	22	AAE10175	Human lipoxin A4 r
4	2500	100.0	470	22	AAE04567	Human G-protein co
5	2500	100.0	470	22	AAB46838	Human G-protein co
6	2500	100.0	470	23	AAE19374	Human G-protein co
7	2500	100.0	505	22	AAG80974	Human nGPCR58 #2.
8	2479	99.2	466	23	AAE17076	Human G-protein co
9	2476	99.0	468	21	AAY71295	Human orphan G pro
10	2476	99.0	468	21	AAB02829	Human G protein co
11	2223	88.9	419	22	AAG80975	Human nGPCR58 #3.
12	2212	88.5	417	22	AAG80962	Human nGPCR58 #1.
13	324.5	13.0	351	23	AAU79035	Human formyl pepti
14	323.5	12.9	351	22	ABB56354	Non-endogenous hum
15	307.5	12.3	350	22	ABB56353	Non-endogenous hum
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19	294.5	11.8	385	20	AAY50138	Mutant human prote
20	294.5	11.8	385	21	AAY45036	Human protease act
21	294.5	11.8	385	22	AAB47623	Human PAR4. Homo
22	294.5	11.8	408	20	AAY50137	FLAG epitope-tagge
23	284	11.4	343	23	AAO21656	Mouse protein homo
24	280	11.2	315	15	AAR48713	G-protein coupled
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26	275	11.0	395	19	AAW44703	Human Th2/B19. Ho
27	266	10.6	372	20	AAW86323	Kidney injury asso
28	265	10.6	333	20	AAY57289	Human BGCKr partia
29	265	10.6	349	20	AAW93170	Human HFIAO41 prot
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36	265	10.6	350	22	AAU08994	Human G protein-co
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44	263	10.5	350	21	AAB02835	Human G protein co
45	262	10.5	350	21	AAB37788	Human TSC7. Homo

ALIGNMENTS

RESULT 1
AAY94267
ID AAY94267 standard; Protein; 470 AA.
XX
AC AAY94267;
XX
DT 01-AUG-2000 (first entry)
XX
DE Human G-protein coupled receptor, AXOR14, protein number 1.
XX
KW Human; G-protein coupled receptor; AXOR14; signal transduction;
KW 7TM receptor; gene therapy; infection; cancer; autoimmunity;
KW Parkinson's disease; cardiovascular disorder; neurological disorder;
KW Huntington's disease; diabetes; obesity; dyskinesias; chromosome 11q13;
KW anorexia; bulimia; osteoporosis; 7 transmembrane receptor.
XX
OS Homo sapiens.
XX
PN WO200026339-A2.
XX
PD 11-MAY-2000.
XX
PF 02-NOV-1999; 99WO-US25791.
XX
PR 03-NOV-1998; 98GB-0024027.
PR 02-MAR-1999; 99US-0260298.
XX
PA (SMIK) SMITHKLINE BEECHAM CORP.
XX
PI Elshourbagy N, Michalovich D;
XX
DR WPI; 2000-365593/31.
DR N-PSDB; AAA15586.

XX
PT New AXOR14 polypeptides and polynucleotides useful for treating e.g.
PT microbial infections, pain, cancers, psychotic and neurological
PT disorders, allergies -
XX
PS Claim 1; Page 36-37; 38pp; English.
XX
CC The present sequence is the human G-protein coupled receptor, AXOR14.
CC G-protein coupled receptors are also known as 7-transmembrane (7TM)
CC receptors. The AXOR14 gene is present on chromosome 11q13. The AXOR14
CC protein functions in hormone signal transduction. AXOR14 protein may be
CC used in the identification of agonists, antagonists or inhibitors that
CC can be used in therapy of microbial infections (e.g. HIV-1 and HIV-2),
CC pain, cancers, psychotic and neurological disorders, allergies, diabetes,
CC obesity, anorexia, bulimia, Parkinson's disease, acute heart failure,
CC hypotension, hypertension, urinary retention, osteoporosis, angina
CC pectoris, myocardial infarction, stroke, benign prostatic hypertrophy,
CC vomiting, dyskinesias or Huntington's disease which may be caused by
CC inappropriate AXOR14 activity or imbalance. The actual gene may also be
CC used in gene therapy for the above disorders.
XX
SQ Sequence 470 AA;

Query Match 100.0%; Score 2500; DB 21; Length 470;
Best Local Similarity 100.0%; Pred. No. 5e-157;
Matches 470; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

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RESULT 2
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ID AAY94268 standard; Protein; 470 AA.
XX
AC AAY94268;
XX
DT 01-AUG-2000 (first entry)
XX
DE Human G-protein coupled receptor, AXOR14, protein number 2.
XX
KW Human; G-protein coupled receptor; AXOR14; signal transduction;
KW 7TM receptor; gene therapy; infection; cancer; autoimmunity;
KW Parkinson's disease; cardiovascular disorder; neurological disorder;
KW Huntington's disease; diabetes; obesity; dyskinesias; chromosome 11q13;
KW anorexia; bulimia; osteoporosis; 7 transmembrane receptor.
XX
OS Homo sapiens.
XX
PN WO200026339-A2.
XX
PD 11-MAY-2000
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PF 02-NOV-1999; 99WO-US25791.
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PR 03-NOV-1998; 98GB-0024027.
PR 02-MAR-1999; 99US-0260298.
XX
PA (SMIK) SMITHKLINE BEECHAM CORP.
XX
PI Elshourbagy N, Michalovich D;
XX
DR WPI; 2000-365593/31.
DR N-PSDB; AAA15587.
XX
PT New AXOR14 polypeptides and polynucleotides useful for treating e.g.
PT microbial infections, pain, cancers, psychotic and neurological
PT disorders, allergies -
XX
PS Claim 14; Page 37-38; 38pp; English.
XX
CC The present sequence is the human G-protein coupled receptor, AXOR14.
CC G-protein coupled receptors are also known as 7-transmembrane (7TM)
CC receptors. The AXOR14 gene is present on chromosome 11q13. The AXOR14
CC protein functions in hormone signal transduction. AXOR14 protein may be
CC used in the identification of agonists, antagonists or inhibitors that
CC can be used in therapy of microbial infections (e.g. HIV-1 and HIV-2),
CC pain, cancers, psychotic and neurological disorders, allergies, diabetes,
CC obesity, anorexia, bulimia, Parkinson's disease, acute heart failure,
CC hypotension, hypertension, urinary retention, osteoporosis, angina
CC pectoris, myocardial infarction, stroke, benign prostatic hypertrophy,
CC vomiting, dyskinesias or Huntington's disease which may be caused by
CC inappropriate AXOR14 activity or imbalance. The actual gene may also be
CC used in gene therapy for the above disorders.
XX
SQ Sequence 470 AA;

Query Match 100.0%; Score 2500; DB 21; Length 470;
Best Local Similarity 100.0%; Pred. No. 5e-157;
Matches 470; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

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Qy       1 MDTTMEADLGATGHRPRTELDDEDSYPQGGWDTVFLVALLLLGLPANGLMAWLAGSQARH 60
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Qy      61 GAGTRLALLLLSLALSDFLFLAAAAFQILEIRHGGHWPLGTAACRFYYFLWGVSYSSGLF 120
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Db     241 TILSAYVVLRLPYQLAQLLYLAFLWDVYSGYLLWEALVYSDYLILLNSCLSPFLCLMASA 300

Qy     301 DLRTLLRSVLSSFAAALCEERPGSFTPTEPQTQLDSEGPTLPEPMAEAQSQMDPVAQPQV 360
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     301 DLRTLLRSVLSSFAAALCEERPGSFTPTEPQTQLDSEGPTLPEPMAEAQSQMDPVAQPQV 360

Qy     361 NPTLQPRSDPTAQPQLNPTAQPQSDPTAQPQLNLMAQPQSDSVAQPQADTNVQTPAPAAS 420
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
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